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UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS

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IN RE: NEW ENGLAND COMPOUNDING MDL No. 2419  
PHARMACY, INC. PRODUCTS Master Dkt.  
LIABILITY LITIGATION 1:13-md-02419-RWZ

- - - - - x  
THIS DOCUMENT RELATES TO ALL SUITS  
AGAINST THE SAINT THOMAS ENTITIES

- - - - - x  
THIS DOCUMENT RELATES TO  
ALL CASES

VIDEOTAPED DEPOSITION OF FRANCIS MCATEER

Wednesday, June 3, 2015

9:10 a.m.

Nutter McClennen & Fish LLP

Seaport West

155 Seaport Boulevard

Boston, Massachusetts 02210

Michelle Keegan, Court Reporter

A P P E A R A N C E S:

GIDEON, COOPER & ESSARY PLC

By: Matthew Cline, Esq.

By: Christopher Tardio, Esq.

315 Deaderick Street #1100

Nashville, Tennessee 37238

Phone: (615) 254-0400

E-mail: matt@gideoncooper.com

E-mail: chris@gideoncooper.com

Counsel for Saint Thomas Outpatient

Neurosurgical Center, LLC; Howell Allen, a

Professional Corporation; John W. Culclasure,

M.D.; Debra V. Schamberg, RN; Specialty Surgery

Center; Crossville, PLLC; Kenneth R. Lister,

M.D.; Kenneth R. Lister, M.D., PC;

Donald E. Jones, M.D.

NUTTER, MCCLENNEN & FISH LLP

By: Sarah P. Kelly, Esq.

Seaport West

155 Seaport Boulevard

Boston, Massachusetts 02210

Phone: (617) 439-2461

E-mail: skelly@nutter.com

Counsel for Saint Thomas Health; Saint Thomas

Network; Saint Thomas West Hospital f/k/a

Saint Thomas Hospital

BLUMBERG & WOLK LLC

By: Christopher M. Wolk, Esq.

158 Delaware Street

Woodbury, New Jersey 08096

Phone: (856) 848-7472

E-mail: cwolk@blumberglawoffices.com

Counsel for Premier Orthopaedic & Sports

Medicine Associates of Southern New Jersey,

LLC; d/b/a Premier Orthopaedic & Sports

Associates, LLC; Premier Orthopaedic

Associates Surgical Center, LLC; Kimberly

Yvette Smith, M.D.; Thomas Dwyer, M.D.;

Richard C. Diverniero, M.D.; Rhaul Shah, M.D.;

and Richard Strauss, M.D.



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1 time we were there.

2 MR. ELLIS: Exhibit 310.

3 (Exhibit Number 310

4 marked for identification)

5 Q. This is an e-mail from Mike Cotugno to Barry  
6 Cadden, cc Fran McAteer, re NECC visit, dated Thursday,  
7 May 3rd, 2012.

8 MR. ELLIS: For the record, it's BW\_118.

9 Q. So this is the next e-mail we could find in the  
10 documents. So this is Michael, and he says to Barry --  
11 Michael Cotugno saying to Barry Cadden, "I just wanted  
12 to make sure we are still on for the BWH vendor audit on  
13 Friday, May 4th, at 8:30." Do you see that?

14 A. Uh-hmm.

15 Q. This is the day before the site visit is about  
16 to occur. Correct?

17 A. Yup.

18 Q. The group from BWH is going to be Cotugno and  
19 Fran McAteer. Correct?

20 MS. ALESSI: Excuse me. He doesn't have the  
21 page that you're reading from in front of him.

22 MR. ELLIS: I'm sorry. Did I just switch pages  
23 here?

24 A. I think we just got one.

1 area which is marked on the blueprint as "shipping and  
2 receiving" and back towards that warehouse area --

3 A. Right over here?

4 Q. Do you see that?

5 A. This area right here.

6 Q. And those actually join. That's open.

7 A. Right.

8 Q. I don't know if you remember, but the  
9 shipping/receiving area opens into the warehouse area in  
10 the back.

11 A. That's right. It did do that. That's some  
12 sort of asphalt in there too.

13 Q. And then the second clean room is in the back.

14 A. Okay. Shown right there.

15 Q. So did you actually, like, look around the  
16 boilers and the roof and the walls of the facility?

17 A. No. We just did a facility tour to get a  
18 general layout and make some observations in the windows  
19 to the clean rooms.

20 Q. So you didn't do an examination where you would  
21 have seen discolorization of equipment or spaces in the  
22 roof?

23 A. No, sir. We would have made -- and probably  
24 the warehouse and the shipping/receiving area may have

1     been full of goods or equipment. We were a little bit  
2     more concerned with segregation, restricted access, and  
3     things of that nature.

4           Q.     So this really was not to look at the real  
5     condition of that building?

6           A.     No. It certainly sends the wrong signal.

7           Q.     Right. These photographs don't look great, do  
8     they?

9           MR. WOLK: Objection.

10          A.     No. But they are in noncritical space.

11          Q.     And I'm not saying they're inside the clean  
12     room. They're not. This is outside the clean room.

13          A.     Yes.

14          Q.     But you didn't see any of what's depicted in  
15     these photos?

16          A.     I did not see anything.

17          Q.     And just to be clear, that big clean room in  
18     the center of the blueprint that you're looking at, you  
19     never went inside that, did you?

20          A.     We did not go inside that.

21          Q.     Now, they have changed their operation  
22     completely?

23          A.     Right.

24          Q.     They had moved into this new clean room.

1 There's a freight anteroom that's -- I don't know if  
2 it's ISO -- I can't read that, what it is -- 8. There's  
3 a prep room that's ISO 7. There's a personal anteroom,  
4 the gowning room, which ISO 7. You have a clean room  
5 right in the center.

6 You hadn't seen that before?

7 A. We hadn't been inside the rooms. We had seen  
8 this layout at Ameridose.

9 Q. Right.

10 A. Yes.

11 Q. Because Ameridose was building it in 2006.

12 A. That's right.

13 Q. So you get there. Did you ask to go into the  
14 clean room?

15 A. Back then, sir, that just was not something  
16 that was allowed.

17 Q. So my question is, did you ask to go -- In the  
18 2012 visit, did you ask Barry Cadden: Can we go into  
19 your clean room?

20 A. No, we didn't. It wasn't one of our methods of  
21 operation for the audit at those dates.

22 If I can amend, we certainly make that as of  
23 the -- after the post meningitis --

24 Q. So you changed your procedures on these audits

1 after the outbreak?

2 A. That's correct. We were, like everyone else,  
3 in a reactive-type mode.

4 MR. TARDIO: I didn't hear.

5 THE WITNESS: I said, like everyone else, we  
6 were in a reactive mode and we looked to make our  
7 procedures more robust. Sorry.

8 Q. So for instance, you didn't see anything like  
9 this inside the clean room. Exhibit 314, just this one  
10 photo.

11 (Exhibit Number 314  
12 marked for identification)

13 Q. I mean, from the --

14 A. No.

15 Q. I said you could look in a little bit from the  
16 window, but you can't see a whole lot from looking in  
17 that outside window, can you?

18 A. That's correct.

19 Q. You really couldn't see the condition of the  
20 floors and the walls and the ceilings?

21 A. Right.

22 Q. You couldn't see if there were spaces in the  
23 tiles in the ceilings, could you?

24 MS. ALESSI: Objection.

1           A.     We were probably at least amenable to that  
2 first part to be able to get a little bit more of that  
3 detail.

4           Q.     But you certainly couldn't see it all  
5 throughout the whole clean room?

6           A.     That's correct.

7           Q.     So when you testified that the materials of use  
8 in the clean room -- when you testified on direct that  
9 the materials seemed adequate, you didn't see dirt, you  
10 didn't see discoloration, well, you didn't go into the  
11 key area. Correct?

12          A.     That's correct.

13                 MR. TARDIO: I object to the form.

14          Q.     This is the clean room that the contaminated  
15 drugs were made in.

16                 MS. KELLY: Objection.

17                 MR. WOLK: Objection.

18          A.     I would have been happy to go in, but --

19                 MS. ALESSI: There's no question.

20          Q.     He wouldn't let you in, would he?

21          A.     That's correct.

22          Q.     He was not going to let you in no matter what.

23                 MS. KELLY: Objection.

24                 MR. WOLK: Objection.



1 compliance with 797 or not. Correct?

2 A. It's certainly an internal quality procedure  
3 that NECC could have utilized.

4 Q. Well, you could have utilized it too. There  
5 are gaps analysis tools. Correct?

6 MR. TARDIO: Objection to form.

7 A. I would utilize that for my clients.

8 Q. Right. You do it for Brigham and Women's  
9 internal pharmacy. Correct?

10 MS. ALESSI: Objection.

11 A. Yes.

12 Q. You didn't do it for NECC during the 2012 site  
13 visit?

14 A. It would have been beyond the scope of this.

15 Q. You never could have done that in 3 hours,  
16 could you?

17 MR. WOLK: Objection. You got to let the  
18 witness answer the question.

19 A. That's correct. I wouldn't be able to.

20 MR. WOLK: He needs to finish the answer.

21 MR. ELLIS: I apologize.

22 Q. You did not do a gap analysis of NECC's USP 797  
23 compliance during the 2012 site visit to NECC, did you?

24 A. A gap analysis was not done on NECC because it

1 was not in the scope of the audit or our responsibility.

2 Q. But you did do it for Brigham and Women's  
3 internal pharmacy. Correct?

4 MS. ALESSI: Objection.

5 A. That's correct.

6 Q. You did not take any surface samples for  
7 testing and bring back to Microbiology Research  
8 Associates where you could have tested some samples, did  
9 you?

10 A. That again was beyond the scope of the audit  
11 and would be an NEC contractual agreement with MRA.

12 Q. You did not review test results for viable  
13 particles, did you?

14 MS. ALESSI: Objection.

15 A. I saw environmental monitoring reports.

16 Q. But you didn't actually look for the test --  
17 the primary test results for viable particles, did you?

18 A. What NECC produced is what I saw.

19 Q. You did not observe the aseptic processing  
20 occurring in the clean room, did you?

21 A. Right. It may have been that at the time we  
22 were doing the walk-through there was no dynamic  
23 conditions ongoing.

24 Q. You did not -- Do you know when Brigham and

1 "And any vendor that wants your business  
2 should be willing to allow you to talk to their  
3 staff. We also are going to do an exhaustive  
4 record review. And that's going to take some  
5 time as well.

6 "And we're going to use a comprehensive  
7 audit tool to document everything that we see  
8 so that we can assure consistency in each site  
9 visit that we do so that we're auditing each of  
10 the vendors in the very same fashion and  
11 looking for the very same information.

12 "I'm Bill Churchill" --  
13 (End of recording)

14 BY MR. ELLIS:

15 Q. Mr. McAteer, when you did the site visits to  
16 NECC in 2008 or 2012, did you ask to talk to the staff  
17 at the facility in private without their boss sitting  
18 there next to them?

19 A. No.

20 MS. KELLY: Objection.

21 Q. Did you have a conversation with Mr. Churchill  
22 about that's really the way to really get to some real  
23 information?

24 MS. KELLY: Objection.